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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,522	06/04/2001	Richard E. Scordato	56154112-7	3542
26453 7590 02/06/2007 BAKER & MCKENZIE LLP 1114 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/06/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/873,522

Applicant(s)

SCORDATO ET AL.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1-5-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8,12-24, and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,12-24,81-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed January 5, 2007 have been fully considered but they are not persuasive.

In reference to the previous 112, first paragraph, rejection applicant states: "that it is clear how the device can operate without the tip being claimed. Nevertheless, for clarification purposes only, independent claim 1 has been amended..." While applicant asserts it is clear how the pipette can function as claimed without the pipette tip, applicant fails to provide where such an assertion is supported by the specification. However applicant's amendment supports the examiner's position. The claim as presently drafted does not positively claim the pipette tip as an element of the handheld pipette. The pipette tip is mentioned in narrative clauses that recite how the handheld pipette is intended to be used when a pipette tip is mounted on the nozzle. The amended claim now states the nozzle portion is configured such that a pipette tip **can be** mounted to an end of the nozzle portion. This is interpreted to mean that the nozzle is structural capable of having a pipette tip mounted there; however applicant is not claiming a pipette tip is an element of the handheld pipettes mounted thereto. One can choose to mount a capillary tube, adapter, or any other structure that fits to the claimed nozzle. However the claim as drafted continues on to narrate how one could possibly operate the device if and when one chooses to mount a pipette tip to the nozzle. The claim further specifies the piston is operable for controlling flow of liquid aspirated into the pipette tip such that the liquid cannot enter into the nozzle portion. As previously

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stated the pipette tip is not positively claimed as an element and is mentioned as an element that can be used in conjunction with the pipette tip to function in as desired by an operator. If a pipette tip were not mounted on the device then the controlling of the piston as mentioned in the claim would not occur for no liquid would enter a pipette tip. In order for the device to function as claimed the pipette tip **must be** positively claimed as being detachably mounted to the end of the nozzle portion. Otherwise as stated above the portions of the claim directed to the pipette tip are considered as intended use of the handheld pipette in conjunction with a separate element. Therefore the prior art is not required to disclose usage and functioning in the same manner but yet be structurally capable of such function. On page 18, applicant states and clearly recognizes claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.

Furthermore it should be noted that in a conventional pipette that comprise a piston/plunger that may or may not have a tip attached to the end of it, an operator can control a stroke length of the plunger manually or preprogrammed in automated pipettes. The stroke length determines the volume, hence one can aspirate a minute volume of liquid which would remain in the tip and never enter the nozzle portion of the device.

It should be noted that "preventing" (previously claimed) an action from occurring and stating that an action is impossible or cannot occur is different. For example one can drive a car and prevent the car from reaching a speed of 70, however this does not mean the car is not structurally capable (cannot reach) of traveling at such a speed.

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Applicant claim as amended now recites the liquid cannot enter into the nozzle portion and thereby cannot move through the body portion. Why is that? Does the nozzle have some type of selective membrane in the nozzle end that allows gas to pass but prevents liquid from passing therethrough? Where is there support in the specification for the device having structure that will not allow liquid to move into the nozzle portion? The examiner fails to find support for such a limitation. The claim is thus considered to contain new matter. In order to avoid new matter rejections, it is requested applicant specify where the limitations of amendments are supported in the original application. As to preventing liquid from entering a body portion by controlling the piston stroke length, this may be accomplished by mounting a tip that has a total volumetric capacity that is greater than the maximum displacement volume of the piston-cylinder pressure assembly.

As to the argument's directed to 102 rejection of the claims based upon Clifford applicant asserts Clifford does not disclose a piston member being operable in the manner recited in the claim. The examiner has previously addressed such argument above. Applicant does recognize the device of Clifford includes a plunger/piston that a user employs to control the flow of fluid into and out of the device. This meets the structural limitation of applicant's claim for the user can control how much fluid as aspirated. Applicant further recognizes that the device allows for a test tube to be attached thereto. As previously stated, the pipette tip is not positively claimed as an element of applicant's pipette, but it is only required that the device have structure which would allow for a pipette tip to be attached thereto. It is possible to, if one so desires, to

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attach or snugly fit a pipette tip with the appropriate dimensions (tips are known to have a tapered opening) onto the device.

On page 17, applicant has underlined the terms the user and plunger itself. It appears as if applicant is stating that applicant's piston member operates to control the flow of fluid without **any** interaction from an operator. This is totally contradictory of applicant's previous statements and disclosure as a whole. The specification, claims, previous remarks, etc. describe and reference how one intends for the device to be held by an operator that subsequently presses a button to control the piston. Is it now applicant's contention that the device is totally automated with no required input from an operator? Does the device include a controller, computer, CPU, or any other electronic device that allows for piston to operate with **no** interaction from an operator? Where is such an assertion supported by the disclosure? Even if the device were automated, there would still be some type of interaction (programming, setting volumetric limits, stroke length, pressing start button) required by the operator. The argument is not commensurate in scope with the originally filed application.

Furthermore applicant describes the operability of the device and how it functions during the aspiration of a liquid. An operator is not required to aspirate a liquid with the claimed device. One can use applicants or any other device how one chooses. Therefore, as previously stated one can simply hold any pipette in the air actuate the plunger and no liquid would enter any portion of the device. There is nothing preventing an operator from actuating the plunger of Clifford such that fluid only enters a pipette tip if one chooses to attach one thereto. This meets the limitation of the claim. If applicant

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intends for weight to be given to how one uses or intends for the device to be used, it is suggested applicant draft method claims in which the specific manner the device is used will be taken into consideration otherwise the claimed invention must be distinguishable from the prior art via structure not by its function or intended use with unclaimed elements.

On page 21 of the remarks applicant clearly argues the intended use/purpose of Clifford rather than the structure of the device. It should be further noted that the device of Clifford is not restricted to use disclosed by the reference. Regardless of purpose, intended use, or process the claimed structure does not change. As with applicant's device, an operator/consumer may use the device in any manner or method to suit their purpose. For example, a chair is intended to be sat in by a person, however one can choose to stand in the chair to reach something (or any other purpose). Regardless of use the structure of the chair remains constant.

Applicant further asserts Math, Kelly, and Strandberg do not suggest nor provide motivation for the pipette to include a piston operable for controlling the liquid aspirated. Math, Kelly, and Strandberg were not cited for disclosing such piston. The primary reference of Clifford discloses a plunger that can be operated as such. The secondary references were cited for their respective teachings of a hook, tip ejection mechanism, and padding as stated.

As such the previous rejection as based upon Clifford is hereby maintain.

As to claim 22 in response to the examiner's position on page 24, applicant has simply restated the examiner's position followed by the claim language. Applicant does

not further provide any arguments or support of why the examiner's position/interpretation is considered invalid. Claim 22 is directed to how one intends for the device to be held, the examiner asserts an operator can choose how the device is arranged in one's hands and furthermore control the pressure which one holds the device with. In other words, the shape of the device is not the only factor in determining how one chooses to hold the device nor determining the pressure applied thereto. The pressure exerted when a person grasps the device may vary from when another grasps the device. Furthermore depending on the individual's strength one can grasp the device how one chooses and squeeze it to apply a pressure exceeding that as recited in the claim. **An operator is not required to hold the pipette the way applicant intends for the device to be held. One can hold it with two hands or mount it in some type of stand or holder if one chooses.** If applicant is attempting to claim a specific shape of the device, it is suggested that applicant take the approach of describing the physical dimensions of the device not how a person's hand is intended to interact with the device. Applicant may also want to consider method claims in which applicant specifies process steps specifying how (position of hand, pressure of grasp, angle of arm, wrist, etc.) holds the device during the performance of a specific process.

On page 25, applicant states claims 1 and 81 have been amended to clarify how the pipette effects aspiration and dispensing of a liquid and controls flow of the liquid into the pipette tip. As previously stated the pipette tip is not positively claimed as a required element of the invention, hence such amendments are considered to be directed to how the device would operate in the event one chose to mount a pipette tip



thereto. The device only functions in the manner claimed when and if a pipette is mounted thereon. The device will not function as such without the pipette tip.

Applicant further asserts the examiner cannot consider any of the elements 64, 62, 65, or 67 nozzle portions since the elements are not in fluid communication with capillary 23. The examiner does not believe applicant assertion is correct, however even it were, the argument is not commensurate in scope with the claim for there is no requirement in the claim to be in fluid communication with a capillary or any other element claimed. The claim actually states liquid cannot enter the nozzle. The nozzle is only required to be mounted at an angle 60 to 80 degrees to the vertical axis and capable of having a pipette mounted thereto. As seen in the figures each of those elements of Clifford meet such requirements specified within the claims. It is the examiner's position that based on the structural description/requirements of "a nozzle" in applicant's claim any of those cited elements may be considered equivalent to the nozzle as claimed.

Applicant repeatedly relies on, recites, and argues the limitation of the piston member and how it is intended function when one chooses to aspirate a fluid is a point of distinction from the prior art. The examiner has addressed the limitation on numerous occasions, by detailing how the examiner interprets the limitation, and how the prior art is interpreted to meet such limitation. The examiner has further made suggestions, proposed questions, and attempted to provide guidance to applicant in response to the amendments and arguments.

On page 27, applicant asserts the examiner failed to provide support for "a number of assertions about the cited devices and references on page 4 of the Final Office Action". The examiner hereby maintains the prior assertions. As previously stated, the drawings (Figures 1-4) of Clifford provide support for the assertions. The figures clearly show elements equivalent to a nozzle angled between 60 to 80 degrees. As to "said at least one button is operated in a direction at a selected angle to said nozzle portion," As seen the figures, the button of Clifford is arranged at a vertical and the nozzle is mounted at an angle to the vertical and button so when the button is actuated is operated at an angle to the nozzle.

As "to a button on said body which controls ejection of a tip from said nozzle portion, said button being shaped to minimize contact pressure on the operator's hand when the button is operated", the only structural requirement is a body to control ejection of a tip. This is met by the 103 rejection that incorporates the teachings Kelly. The remaining portion of the phrase is not considered further structurally limiting for reasons stated above.

As to "said body portion has a stable base permitting said pipette to stand on a surface with the vertical central axis of the body portion substantially perpendicular to the surface", there is no clear recitation of structure of what constitutes a stable base. What does applicant consider "a stable base"? It is only required that the device have the ability to sit on a surface. As illustrated by the figures there is nothing that would prevent one from sitting the device of Clifford on a surface (such as a table edge) where it could remain "stable". Is a stable base constituted by some specific structural

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dimensions? Stability of an object does not totally depend on its structure but it also depends on the structural characteristics of the surface which one intends for it to be placed.

As to "wherein said nozzle portion is operable for receiving the pipette tip, including at least the angle  $\theta$  of said nozzle portion to the vertical central axis of said body portion and length of said tip affixed to said nozzle portion, are selected such that said tip does not touch a surface on which the pipette is standing", as previously stated the pipette tip is not positively claimed, hence any subsequent language directed thereto is not further limiting. The only structural requirement is that the nozzle be capable of having a pipette tip mounted thereto (addressed above). As previously stated, Clifford discloses elements that are equivalent to the claim nozzle. And furthermore an operator can choose to connect a pipette of any desired dimensions including one of the length as mentioned in the claim. Furthermore such a statement would also be affected by the shape of the surface. What if the surface is only flat in the region on which the base sits, but the surface has a steep rise thereafter? Applicant is attempting to define the structure relative to unclaimed elements with which the device may be used.

As to "said body portion has a bottom which is removable at least in part to provide access to the pipette," Clifford discloses the head member 12 and holder 11 (body, bottom) are held together via screw 15 (see Figures and column 2, lines 14-15). Such screw allows for the bottom to be removed.

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As to "an adapter selectively mountable to said body portion, said adapter adjusting the size of said body portion to better fit operator hand size", the only structural requirement is an element, adapter, mounted to said body. The head member 12 of Clifford is mounted to the body 11. The remaining portion of the claim is not considered further limiting. The claim employs relative language. There is no standard size hand for an operator and what feels "better" to one operator may not feel better to the next operator. Who determines what is a "better fit" and there is no means of comparison as to base what is better or worse.

### ***Specification***

2. The disclosure is objected to because of the following informalities: The specification is missing the co-pending application serial numbers on page 7.

Appropriate correction is required.

### ***Claim Interpretations***

The broad structural requirements of claim 1 is a body portion that has a longer vertical axis than horizontal axis (which is relative to one's viewing perspective), a nozzle portion connected to the body portion at an angle 60 to 90 degrees relative to the vertical axis, a button on top of the body aligned with the vertical axis, and a piston member that can be operated (manually or automated) to control an amount of liquid aspirated (if one chooses to use the device for aspiration), wherein the nozzle has a end portion structure that optionally allows for a pipette tip (or any other structure) to be mounted thereon.

It should further be noted that those claims (4-5) directed to how an operator holds the pipette or positions his/her body are directed to intended use or process limitations. The claims are not structurally limiting of the device. Any operator can hold the device how they choose and position their body or the pipette at any angle or position they choose. The force exerted by those who choose to use the device is relative. The manner in which applicant intends for the device to be used, held, or positioned does not further limit the structure. Applicant has amended claim 4 to recite a "natural position". This is relative to an individual user of the device thus this is not structurally limiting of the device. Applicant specification states "such design should also facilitate the user's joints, including elbow, shoulder and wrist/hand being held in **their** neutral or natural position during pipetting operations,"

As implied by the passage an individual has his/her own natural position which does not change the structure of the pipette, but may change the way someone chooses to use the pipette.

As to the phrase "ergonomically shaped", this term does not imply nor specify any particular or defined shape. Applicant has not defined the term as consisting of any particular shape. What may be considered ergonomic for one person may not be ergonomic for the next. Therefore, such a recitation and others which are directed to use of the term do not further structurally limit the device.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8, 12-24, and 81-93 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The tip and its relationship to the nozzle is considered critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). While the specification is enable for one operating a plunger of a device to aspirate dispense liquid into and from a tip included thereon and preventing it from entering a nozzle. The specification is not enabled for performing as such without a tip being present if the tip is not present then where is the liquid aspirated to or dispensed from? The tip is not positively claimed as an element of the device hence it's not required however the device cannot function as claimed without the tip being mounted onto the nozzle end. Furthermore the specification is not enabled such that structure is provided where liquid cannot enter the nozzle (see Response to Arguments).

3. Claims 1-8, 12-24, and 81-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims 1 and 81 contain new matter as explained above (see Response to Arguments).

***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 4-5, 12-13, and 15-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Clifford US 3,246,559.

Clifford discloses a pipetting device with an angled nozzle 64. The device is capable of aspirating and dispensing fluid into and from a cuvette 25 (as described in column 4, lines 31-49).

As seen in the figures, there is button centrally located on the head.

The holder 11 and head member 12 (including the button) are removable from one another.

The head member may be considered an adapter for when attached it changes the size of the device.

### ***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clifford as applied to claims 1-2, 4-5, 12-13, and 15-24 above, and further in view of Math US 2,796,204.

Math discloses the combination of a dispensing device 10 attached to a bottle 12 (bottle or bottom portion removable). As seen in the figures the device is capable of being held in one's hand and operated (via button or tab 36 substantially near the central axis) to dispense or aspirate a liquid via spout 28.

The examiner asserts that the handle element 37 may be considered a hook or the spring element 42 (as seen in the figure). The degree of the bend in the spring/hook 42 depends upon how far the tab/button 36 is depressed. The spring/hook is removable/replaceable via a screw (not labeled) and or collar 40.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Clifford to include a hook element such as that of Math in order to provide a means for holding and carrying the device.

8. Claims 14 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clifford as applied to claims 1-2, 4-5, 12-13, and 15-24 above, and further in view of Kelly et al. US 6,737,023.

Clifford does not disclose the device as comprising a mechanism for ejecting tip.

Kelly et al. discloses air displacement pipettes including a novel mounting shaft and a unique pipette tip tailored to the mounting shaft such that the tip is easily insertable by a pipette user onto the shaft to a fluid tight position in which the tip is secured against undesired lateral rocking on or displacement from the shaft and, after use, is easily ejectable from the shaft by the pipette user; such tip insertion and ejection requiring the pipette user to only exert axial tip insertion and ejection forces of about one pound or less thereby substantially eliminating all risk of repetitive motion injury to the pipette user.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Clifford to incorporate the tip ejection mechanism as



taught by Kelly et al. in order to remove and replace the tip 19 with minimal risk of injury to the user.

9. Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clifford as applied to claim 1 above, and further in view of Strandberg et al. US 5983733.

Clifford does not disclose the inventions as comprising a padding material.

Strandberg et al. discloses a hand-held pipette comprising, in combination: a hand receiving portion having an ergonomic contour, a combination fluid inlet and outlet located adjacent the hand portion, means for introducing and dispensing fluid into and out of the pipette via the inlet and outlet, and a resilient cushion disposed along an outer periphery of the hand receiving portion to reduce fatigue and trauma to a technician operating the pipette.

It would have been obvious to one of ordinary skill at the time of the invention to modify either of the devices of Clifford to incorporate the cushion or padding as taught by Strandberg in order to relieve or reduce fatigue to an operators hand when holding the devices.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



brg

BRIAN R. GORDON  
PRIMARY EXAMINER